REMARKS

Section 112, first paragraph - new matter

Claims 60-63 and 80-82 are rejected under 35 USC Section 112, first paragraph as failing to comply with the written description requirement. As to the insertion of the modifier "ex vivo" in the claims, the Examiner asserts that he fails to find that the claimed complexes of a polypeptide having an altered Fc region, and an FcγR allotype are disclosed at pages 38-40. The Examiner contends that the complexes disclosed at pages 38-40 consist of more components.

Applicants respectfully traverse the rejection. The specification clearly describes the claimed Fc mutants, and explains they have altered binding for FcγR allotypes, see, e.g. page 9, line 31 through to line 5 on page 10. The skilled person would understand that such binding can be assessed ex vivo. The receptor binding assay and immune complexes referenced on pages 38-40, are merely one embodiment of an assay for evaluating binding of the Fc mutants to FcγR allotypes. Moreover, as explained in the paragraph bridging pages 98-99, binding of the Fc mutants to different FcγR allotypes was assessed using *both* the low affinity receptor binding assay (which evaluated binding of an IgG complex, of the type described on pages 38-40, to the FcγR allotype), as well as the high affinity FcγR binding assay (which analyzes binding of IgG monomer to the FcγR allotype). In addition, as explained at page 106, second paragraph, binding of the *monomeric* Fc mutant to the FcγR allotype (in contrast to hexameric complexes used in the ELISA-format assay) was also evaluated in a cell-based assay. Such ex vivo high affinity binding assay, and cell-based assay, would not involve formation of the immune complexes to which the Examiner refers in the Office Action. Thus, Applicants submit that the specification clearly describes the ex vivo complexes set forth in claims 60-63 and 80-82 herein comprising the Fc mutant noncovalently bound to an FcγR allotype (such as an FcγRIIIA-Phe158 allotype). Hence, Applicants submit that the invention set forth in claims 60-63 and 80-82 is described in the specification in a manner that satisfies the Section 112, first paragraph written description requirement. Reconsideration and withdrawal of the rejection is respectfully requested.

Section 101 and Section 112, first paragraph - utility

The Examiner maintains the rejection that claims 60-63 and 80-82 lack utility under 35 USC Section 101 and Section 112, first paragraph.

Applicants submit that the specification describes how to use the ex vivo mutants set forth in the pending claims. In particular, the specification explains that the claimed Fc mutants have altered binding to FcγR allotypes, and therefore, formation of the ex vivo complex is useful, among other things, for evaluating binding of the Fc mutants to the FcγR allotype. Such immune complexes are not limited to the types of immune complexes referenced in the Office Action, but include ex vivo complexes such as those formed in the high affinity FcγR binding assay and cell-based assay, as noted above.

Reconsideration and withdrawal of the Section 101 and 112, first paragraph utility rejections is respectfully requested in view of the above.

Section 102 and 103

Claims 60-63 and 80-82 are rejected under 35 USC Section 102(b) or 102(e) as being anticipated, or in the alternative, under 35 USC Section 103(a) as obvious over Idusogie et al. WO99/51642 or US Patent No. 6,242,195. Claims 60-63 and 80-82 are rejected under 35 USC Section 102(e) as being anticipated by, or in the alternative, under 35 USC Section 103(a) as obvious over Idusogie et al. US Patent No. 6,528,624.

The Examiner states that he sees 'the limitation of "ex vivo" as being essentially a product by process limitation; as such the nature of the noncovalent bond must be considered for what it is per se and not how it may have been formed.'

Without acquiescing in the rejection, and in order to expedite prosecution, claim 60 is amended herein to refer to an "ex vivo complex comprising a polypeptide comprising a variant Fc region with increased affinity for an FcγR allotype noncovalently bound to an FcγR allotype or an extracellular domain thereof," and claim 80 is amended to refer to an "ex vivo complex comprising a polypeptide comprising a variant Fc region noncovalently bound to an FcγRIIIA-Phe158 allotype or an extracellular domain thereof." Applicants submit that the claim amendments obviate the Examiner's basis for rejecting the claims, thus rendering the rejections moot. Reconsideration and withdrawal of the Section 102 and 103 rejections is respectfully requested.

37 CFR 1.75

Applicants submit that the rewording of the claims obviates any objection that claims 63 and 80 are "substantial duplicates" of each other. Reconsideration and withdrawal of the objection to claims 63 and 80 under 37 CFR 1.75 is respectfully requested.

Applicants believe this application is now in condition for allowance and look forward to early notification to that effect.

Respectfully submitted,
GENENTECH, INC.

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By: _____
Wendy M. Lee
Reg. No. 40,378
Telephone No. (650) 225-1994